

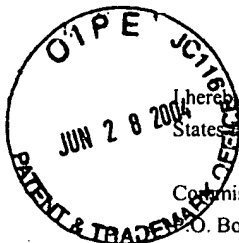
JPA

<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	10/661,366
		Filing Date	September 12, 2003
		First Named Inventor	Kerschbaumer, Randolph
		Art Unit	Not yet known
		Examiner Name	Not yet known
Total Number of Pages in This Submission		Attorney Docket Number	20695C-006400US

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) <i>(please identify below):</i> Return Postcard, copy of one (1) cited co-pending application and forty-seven (47) cited references
Remarks		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual	Townsend and Townsend and Crew LLP Scott L. Aussenhus Reg. No. 42,271
Signature	
Date	June 25, 2004

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Nicole Wartell		
Signature		Date	June 25, 2004



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PATENT  
Attorney Docket No.: 20695C-006400US

On June 25, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: 

Nicole M. Wartell

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Randolf Kerschbaumer et al.

Application No.: 10/661,366

Filed: September 12, 2003

For: FACTOR IXA SPECIFIC  
ANTIBODIES DISPLAYING FACTOR  
VIII LIKE ACTIVITY

Examiner: Not yet known

Art Unit: 1614

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR 1.98(a)(2), copies of the foreign patents and non-patent literature references are enclosed herewith. The U.S. patents are not enclosed in accordance with the Patent Office waiver issued August 5, 2003 in the Official Gazette, which states as follows:

The Office hereby waives the requirement under 37 CFR 1.98

(a)(2)(i) for submitting a copy of each cited U.S. patent and each

U.S. patent application publication for all U.S. national patent

applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b).

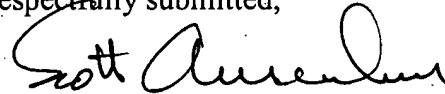
Applicants also wish to make the Examiner aware of the following co-pending patent application: U.S. Patent App. No. 09/661,992, filed 09/14/2000, Applicant SCHEIFLINGER et al., Attorney Docket No. 20695C-005900US. To comply with 37 CFR §1.98(a)(2)(iii), the specifications, drawings and claims for this application are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

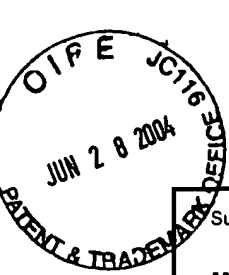
Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Scott L. Ausenhus  
Reg. No. 42,271

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 303-571-4000  
Fax: 303-571-4321  
SLA:nmb  
60124029 v1



<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/661,366		
		Filing Date	September 12, 2003		
		First Named Inventor	Kerschbaumer, Randolph		
		Art Unit	1614		
		Examiner Name	Not yet known		
Sheet	1	of	4	Attorney Docket Number	20695C-006400US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	A1	US-4,395,396	07-26-1983	Eibl et al.	
	A2	US-4,873,316	10-10-1989	Meade et al.	
	A3	US-5,932,706	08-03-1999	Mertens et al.	
	A4	US-6,632,927 B2	10-14-2003	Adair et al.	
	A5	US-6,391,299 B1	05-21-2002	Blackburn et al.	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	PCT	WO 95/13300	A1	05-18-1995			<input type="checkbox"/>
	B2	PCT	WO 97/26010	A1	07-24-1997			<input type="checkbox"/>
	B3	PCT	WO 99/01476	A1	01-14-1999			<input type="checkbox"/>

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

60124029 v1

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/661,366		
		Filing Date	September 12, 2003		
		First Named Inventor	Kerschbaumer, Randolph		
		Art Unit	1614		
		Examiner Name	Not yet known		
Sheet	2	of	4	Attorney Docket Number	20695C-006400US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Ames, R.S. et al., "Conversion of Murine Fabs Isolated From a Combinatorial Phage Display Library to Full Length immunoglobulins", <i>J. Immunol. Methods</i> , 1995, pp. 177-186.	
	C2	Bajaj, S. P. et al., A Monoclonal Antibody to Factor IX That Inhibits the Factor V111: Ca Potentiation of FactorX Activation, <i>The Journal of Biological Chemistry</i> , 260(21), pp. 11574-11580 (1985).	
	C3	Bessos, H., et al., The Characterization of a Panel of Monoclonal Antibodies to Human Coagulation Factor IX, <i>Thrombosis Research</i> , 40, pp. 863-867 (1985).	
	C4	Cao, Y. et al., Bispecific Antibodies as Novel Bioconjugates, <i>Bioconjugate Chemistry</i> , 9(6), pp. 635-644 (1998).	
	C5	Cohen, F.E., et al., The Combinatorial Approach, Protein Structure Prediction-A Practical Approach (Ed. M.J.E. Stenberg), Oxford University Press, Ch. 9, pp. 207-227 (1996).	
	C6	Engelhardt, O., et al., <i>Two-Step Cloning of Antibody Variable Domains in a Phage Display Vector</i> , <i>Biotechniques</i> , 17, p. 44-46 (1994).	
	C7	Esser, C., et al., Immunoglobulin Class Switching: Molecular and Cellular Analysis, <i>Annu. Rev. Immunol.</i> , 8, p. 717-735 (1990).	
	C8	Evan, G. I., et al., Isolation of Monoclonal Antibodies Specific for Human c-myc Proto-Oncogene Product, <i>Mol. Cell. Biol.</i> , 5(12), p. 3610-3616 (1985).	
	C9	Fay, P.J., et al., <i>Factor Villa A2 Subunit Residues 558-565 Represent a Factor IXa Interactive Site</i> , <i>Journal of Biological Chemistry</i> , 269(32), p. 20522-20527 (1994).	
	C10	Frazier, D., et al., Mapping of Monoclonal Antibodies to Human Factor IX, <i>Blood</i> , 74(3), p. 971-977 (1989).	
	C11	Gao, C., et al., Making Artificial Antibodies: A Format for Phage Display of Combinatorial Heterodimeric Arrays, <i>Proc. Natl. Acad. Sci.</i> , 96, p. 6025-6030 (1999).	
	C12	Grassy, G., et al., Computer-Assisted Rational Design of Immunosuppressive Compounds, <i>Nature Biotechnology</i> , 16, p. 748-752 (1998).	
	C13	Greer, J., et al., Application of the Three-Dimensional Structures of Protein Target Molecules in Structure-Based Drug Design, <i>Journal of Medicinal Chemistry</i> , 37(8), p. 1035-1054 (1994).	
	C14	Harlow, E., et al., 2. Antibody Molecules, <i>Antibodies-A Laboratory Manual</i> ; pp. 7-22 (1988).	
	C15	Harlow, E., et al., 3. Antibody-Antigen Interactions, <i>Antibodies-A Laboratory Manual</i> ; p. 23-35(1988).	
	C16	Harlow, E., et al., 6. Monoclonal Antibodies, <i>Antibodies-A Laboratory Manual</i> ; p. 139-243(1988).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/661,366	
			Filing Date	September 12, 2003	
			First Named Inventor	Kerschbaumer, Randolph	
			Art Unit	1614	
Examiner Name	Not yet known				
Attorney Docket Number	20695C-006400US				
Sheet	3	of	4		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C17	Hochuli, E., et al., Genetic Approach to Facilitate Purification of Recombinant Proteins with a Novel Metal Chelate Adsorbent, Biotechnology, 6, p. 1321-1325 (1988).	
	C18	Huston, J. S., et al., Medical Applications of Single-Chain Antibodies, Intern. Rev. Immunol., 10, p. 195-217 (1993).	
	C19	Jones, D.T., et al., Protein Folds and Their Recognition from Sequence, Protein Structure Prediction-A Practical Approach (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 8, p. 174-206 (1996).	
	C20	Jones, P.T., et al., Replacing the Complementarity-Determining Regions in a Human Antibody with Those from a Mouse, Nature, 321, p. 522-525 (1986).	
	C21	Jorquera, J. I., et al., Synthetic Peptides Derived from Residues 698 to 710 of Factor VtII Inhibit Factor IXa Activity, Circulation, 86, Abstract No. 2725, p. 1-685 (1992).	
	C22	Karpen, M.E., et al., Modelling Protein Conformation by Molecular Mechanics and Dynamics, Protein Structure Prediction-A Practical Approach (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 10, p. 229-261 (1996).	
	C23	Kemp, D.S., Peptidomimetics and the Template Approach to Nucleation of B-sheets and a helices in Peptides, TIBTECH, 8, p. 249-255 (1990).	
	C24	Kerschbaumer, R.J. et al., Single-Chain Fv Fusion Proteins Suitable as Coating and Detecting Reagents in a Double Antibody Sandwich Enzyme-Linked Immunosorbent Assay, Analytical Biochemistry, 249, p. 219-227 (1997).	
	C25	Kerschbaumer, R.J., et al, pDAP2: A Vector for Construction of Alkaline Phosphatase Fusion Proteins, immunotechnology, 2, p. 145-150 (1996).	
	C26	Lane, R. D., A Short-Duration Polyethylene Glycol Fusion Technique for Increasing Production of Monoclonal Antibody-Secreting Hybridomas, Journal of Immunological Methods, 81, p. 223-227 (1985).	
	C27	Lenting, P.J., et al., The Sequence Glu <sup>19</sup> F-Lys <sup>20</sup> d of Human Blood Coagulation Factor VIII Comprises a Binding Site for Activated Factor IX, Journal of Biological Chemistry, 271(4), p. 1935-1940 (1996).	
	C28	Liles, D. K., et al, The Factor VIII Peptide Consisting of Amino Acids 698 to 712 Enhances Factor IXa Cleavage of FactorX, Blood, 90(1), Abstract No. 2054, p. 463a (1997).	
	C29	Lin, H-F., et al, A Coagulation Factor IX-Deficient Mouse Model for Human Hemophilia B, Blood, 90(10), p. 3962-3966 (1997).	
	C30	Malik, P., et al., Multiple Display of Foreign Peptide Epitopes on Filamentous Bacteriophage Virions, Phage Display of Peptides and Proteins (Ed. B. K. Kay et al.), Academic Press, p. 127-139 (1996).	
	C31	Mann, K.G., et al., Surface-Dependent Reactions of the Vitamin K-Dependent Enzyme Complexes, Blood, 76(1), p. 1-16 (1990).	
	C32	Mikaelsson, M., et al., Standardization of VIII:C Assays: A Manufacturer's View, Scandinavian Journal of Haematology (Ed. Nilsson et al.), 33, p. 79-86 (1984).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/661,366	
			Filing Date	September 12, 2003	
			First Named Inventor	Kerschbaumer, Randolph	
			Art Unit	1614	
			Examiner Name	Not yet known	
Sheet	4	of	4	Attorney Docket Number	20695C-006400US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C33	Nilsson, I.M. et al., Induction of Split Tolerance and Clinical Cure in High-Responding Hemophiliacs with Factor IX Antibodies, <i>Proc. Natl. Acad. Sci. USA</i> , 83, p. 9169-9173 (1986).	
	C34	PANKA et al. "Variable region framework differences result in decreased or increased affinity of variant anti-digoxin antibodies." <i>Proc. Natl. Acad. Sci. USA</i> , May 1988, pp. 3080-3084, Vol. 85, No. 9.	
	C35	Persic, L., et al., An Integrated Vector System For The Eukaryotic Expression of Antibodies or Their Fragments After Selection From Phase Display Libraries, <i>Gene</i> , p. 9-18 (1997).	
	C36	Pluckthun, A., et al., New Protein Engineering Approaches to Multivalent and Bispecific Antibody Fragments, <i>Immunotechnology</i> , 3, p. 83-105 (1997).	
	C37	Raag, R., et al., Single-Chain Fvs, <i>FASEB Journal</i> , 9(1), pp. 73-80 (1995).	
	C38	Rees, A.R., et al., Antibody Combining Sites: Structure and Prediction, <i>Protein Structure Prediction-A Practical Approach</i> (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 7, p. 141-172 (1996).	
	C39	Roitt, LM., et al., Molecules which Recognize Antigen, <i>Immunology</i> , 2nd Edition, p. 5.1-5.11(1989).	
	C40	RUDIHOFF et al. "Single amino acid substitution altering antigen-binding specificity." <i>Proc. Natl. Acad. Sci. USA</i> , 1982, pp. 1979-1983, Vol. 79, No. 6.	
	C41	Sadler, J.E., et al., Hemophilia A, Hemophilia B, and von Willebrand's Disease, <i>The Molecular Basis of Blood Diseases</i> (Ed. G. Stamatoyannopoulos et al.), p. 575-630 (1987).	
	C42	Vaughan, T.J., et al., Human Antibodies By Design, <i>Nature Biotechnology</i> , p. 535-539(1998).	
	C43	Winter, G., et al., Making Antibodies by Phage Display Technology, <i>Annu. Rev. Immunol.</i> , 12, p. 433-455 (1994).	
	C44	Zhong, D., et al., Some Human Inhibitor Antibodies Interfere with Factor VIII Binding to Factor IX, <i>Blood</i> , 92(1), p. 136-142 (1998).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.